OCT - 4 2000

H&C Medical Devices FDA DOCUMENT NUMBER: K002074

5. Summary of Safety and Effectiveness

AB CARDIETTE Daedalus View Base

and

AB CARDIETTE Daedalus View Hes

5.1 Date of application: 07/06/2000

5.2 Applicant's name and address: H&C Medical Devices spa
Via Pisa 250
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(Milan) ITALY

5.3 Contact person: Mr. Attilio Castelli
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5.4 Device Trade Name
AB CARDIETTE Daedalus View Base and AB CARDIETTTE Daedalus View Hes

5.5 Device Common Name
ECG Interpretive Electrocardiograph

5.6 Device Classification Name

CFR 870.2340 Electrocardiograph	Class II	74DPS
CFR 870.2340 System, ECG Analysis	Class III	74LOS

5.7 Predicate Device
The legally marketed device to which equivalence is being claimed is:

Manufacturer Name	Applicant Name	Predicate Device	510(k) Number
Elettronica Trentina	Qmed Inc.	Interp 1000	K921476

The safety features of the AB CARDIETTE Daedalus View Base and AB CARDIETTE Daedalus View Hes are identical to those of the predicate Interp 1000. The performances of AB CARDIETTE Daedalus View Base and AB CARDIETTE Daedalus View Hes have been increased with respect to the predicate Interp 1000

Summary of Safety and Effectiveness (con't)

and are summarized in table 5.7.1. The Interpretation Program implemented in AB CARDIETTE Daedalus View Hes is identical to the one implemented in the predicate Interp 1000 as far as Interpretation algorythm is concerned. Some minor changes related to raw data formatting and scaling have been performed by the developer Medizinische Hochschule Hannover in order to optimize memory, better organize COMMON areas of data and to fix an overflow error which did not cause output measurements errors.

Table 5.7.1

Parameter	AB CARDIETTE DAEDALUS VIEW Base and Hes	Predicate Device INTERP 1000
RECORDER		
Input dynamic range	+/-300mV @ DC 25 mV within the bandpass	+/-300mV @ DC 6.4 mV within the bandpass
Frequency response	0.05 – 150 Hz (-3dB)	0.05 – 100 Hz (-3dB)
A/D conversion	14 bits	12 bits
Leads	12 Standard / 12 Cabrera	12 Standard
Sensitivity	1.25 2.5 5 10 20 40 mm/mV +/-5%	5,10,20 mm/mV +/-5%
Writing system	Thermal head 210 mm 8 dots/mm	Thermal head 108 mm 8 dots/mm
Printed channels	3/4/6/12	3/6
Paper speed	1.25 2.5 5 10 12.5 mm/s +/-10% 25 50mm/s +/-5%	5 mm/s +/- 10% 25 50 +/-5%
Thermal paper	DOTCARD 210 mm	DOTCARD 120 mm
Mode of operation	Manual, Manual delayed and Automatic recording	Manual, Automatic recording
Input/output	RS 232 standard digital port	2 analog inputs 3 analog outputs
DISPLAY		
Size	VGA 640 x 480 pixels	N/a
N° of displayed channels	3 / 6	N/a
Traces speed	1.25 2.5 5 10 12.5 25 50mm/s	N/a
Sensitivity	1.25 2.5 5 10 20 40 mm/mV	N/a

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5.8 Device description

AB CARDIETTE Daedalus View Base and Daedalus View Hes are two electrocardiographs providing the following characteristics:

Daedalus View Base

- Mains and internal battery operation
- Manual acquisition of the 12 Standard Leads
- Simultaneous acquisition of the 12 Standard Leads
- Storage of 10 seconds of acquired ecg signal
- Ecg printout of either 3, 4, 6 or 12 leads per page
- Copy function of the stored ecg
- Patient input data for identification
- High resolution digital thermal printer
- VGA electroluminescent display for signal display and user friendly interface
- Digital filters for AC interference suppression, base-line drift and muscolar tremour suppression
- Grid printout on white paper

Daedalus ViewHes

Same characteristics as above with the following additional fatures:

- Patient input data for Interpretation, identification and filing purposes
- Possibility to file recorded ecg's on a Personal Computer or Workstation via RS232 interface
- Interpretation Program Hannover Ecg System (HES) providing the following report:
  - Representatives Templates of each lead including markers on fiducial points
  - Summary of mean measurements
  - Rythm Analysys Statements
  - Rythm graphical representation
  - Signal noise detection and information
  - Specific findings on QRS complex
  - Conduction statements
  - QRS T Diagnostic Statements
  - Summary of measurements performed on each lead

Summary of Safety and Effectiveness (con't)

5.9 Intended use

AB CARDIETTE Daedalus View Base and Hes are two electrocardiographcharacterized as follows:

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Daedalus View Base is a basic standard electrocardiograph.
Daedalus View Hes is equivalent to the Base version but provided with an additional program for automated ecg analysis.

Intended use is equivalent to the intended use of the predicate Interp 1000.
More specifically:
Both equipments are intended for use in routine ecg recording in physician practice and/or hospital. The electrical heart activity is detected by means of two or more electrocardiograph electrodes and can be visualized on a digital display and recorded on thermal paper.

Intended use for non interpretive applications (both versions View Base and Hes) cover the full range of patient population with no limitiations with respect to age, sex and race of the patient.

The interpretation program is intended to provide a diagnostic support to the physician for the ecg evaluation on rythm and morphology.

5.10 Comparison of technological characteristics

The basic technological characteristics differences between AB CARDIETTE Daedalus View Base and Daedalus View Hes and predicate device Interp 1000 can be summarized as follows:

- Use of smt technology versus conventional technology
- Larger printer (A4/letter format)
- Large LCD VGA 640x480 display)
- Digital RS 232 interface

The essential equipments achitecture with respect to safety has not been changed. The processing unit has not been changed as well. Patient input data and target population are the same.
Some better performances have been reached by increasing the input dynamic range and the bandwidth. All increase of performances have been introduced in order to meet the requirements of the following draft standard:

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62D/60601-3-2/ed.1, 1997	Medical Electrical Equipment, Part 3: Particular requirements for the essential performances of recording and analyzing electrocardiographs

5.11 Non clinical tests used for Substantial Equivalence Determination

Full safety tests according to EN60601-1 and IEC 601-2 25 have been performed on AB CARDIETTE Daedalus View Base and Daedalus View Hes. Tests have shown full compliance with these standards.
Both equipments have been subject to Electromagnetic Compatibility testing procedures according to EN60601-1-2 standard. Tests have shown full compliance with this standard.
The correct implementation of the interpretation program has also been tested and validated.
The interpretation program has not been changed. It has been intensively tested and validated by the developer Medizinische Hochschule Hannover. Test results have been published on the New England Journal of Medecine 325:1767-1773 December 19, 1991 under the title:

The Diagnostic Performance of Computer Programs for the Interpretation of Electrocardiograms.

The results shown in this study have demonstrated the quality and accuracy of the HES program with respect to other commercially availabe programs.
Moreover, both equipments are marketed worldwide since 1998 under the names CARDIETTE Daedalus View Base and CARDIETTE Daedalus View Hes.
No adverse working conditions have been claimed and filed up to date.
Both equipments are CE marked according to 93/42/CEE Medical Device Directive.

5.12 Conclusions

Based on the above, H&C Medical Devices belives that AB CARDIETTE Daedalus View Base and Daedalus View Hes are substantially equivalent to Interp 1000.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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NOV 1 5 2000

Mr. Attilio Castelli
Managing Director
H & C Medical Devices Spa
Via Pisa 250
20099 Sesto San Giovanni
(Milan) ITALY

Re: K002074
Trade Name: AB CARDIETTE Daedalus View base and Hes
Regulatory Class: II (two)
Product Code: 74 DPS
Dated: July 6, 2000
Received: July 10, 2000

Dear Mr. Castelli:

This letter corrects our substantially equivalent letter of October 4, 2000 regarding the regulatory class (Class III) and product code (LOS). The AB CARDIETTE Daedalus View base and Hes device was assigned an incorrect regulatory class and product code.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to continue marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Device Name: AB CARDIETTE Daedalus View Base and AB CARDIETTE Daedalus View Hes.

Indication for Use:

AB CARDIETTE Daedalus View Base and Hes are two electrocardiograph recorders based on the same hardware.
Daedalus View Base is a basic standard electrocardiograph.
Daedalus View Hes is equivalent to the Base version but provided with an additional program for automated ecg analysis.

Both equipments are intended for use in routine ecg recording in physician practice and/or hospital. The electrical heart activity is detected by means of two or more electrocardiograph electrodes and can be visualized on a digital display and recorded on thermal paper.

Intended use for non interpretive applications (both versions View Base and Hes) cover the full range of patient population with no limitiations with respect to age, sex and race of the patient.

The interpretation program is intended to provide a diagnostic support to the physician for the ecg evaluation on rythm and morphology.

Interpretation Statements must be overwieved and approved by trained Physician's. Interpretation statements just represent a partial qualitative and quantitative information of the general patient cardiovascular condition: no therapy or drugs can be subministrated based solely on Interpretation statements.

The equipments are intended to be used by trained medical personnel or physician's.

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K002074